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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,842	08/04/2003	Keith Rosiello	350930-0200 (ZQI-127/US)	5671
48329 7590 10/10/2007 FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER SORKIN, DAVID L	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 10/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/633,842		ROSIELLO, KEITH	
	<b>Examiner</b>		<b>Art Unit</b>	
	David L. Sorkin		1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8,9,11,12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,9,11,12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 September 2007 has been entered.

### ***Claim Objections***

2. Applicant is advised that should claim 9 be found allowable, claim 11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Claim 9 already requires an axial opening on both the first side and the second side of the flexible chamber. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Firstly, because claim 19 first recites "comprising a first side

with an axial opening and a second side with an axial opening" and then recites "wherein either or both the first side and the second side of each chamber including an axial opening", the scope of the claim is unclear. Secondly, recitations of "the flexible chamber" are unclear because a plurality of flexible chambers is recited and it is unclear if each of the flexible chambers is being referenced or if a particular one of the chambers is being referenced.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-6, 8, 9, 11, 12 and 14-20 rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/28451. Regarding claim 1, WO '451 discloses a flexible chamber (31,32,41,42,71,72,81 or 82; or a plurality thereof) comprising a first side (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side may be considered the left side of the hub) with an axial opening (such as 23 or 63) and a second side (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side may be considered the right side of the hub) with an axial opening (such as 23 or 63), wherein a first end of the expandable wall is attached to a circumference of the first side of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for

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example the left and right halves of the expandable wall of 32 as depicted in Fig. 3; in other words the “two sheets of flexible material mentioned on page 3, lines 9-11), wherein a first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber and wherein a second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber (see Fig. 3; page 3, lines 9-11), wherein the chamber is sterilized (see page 1, lines 11-13; page 5, line 25) and adaptable to a continuous centrifuge (see page 2, lines 5-6). Regarding claim 4, the flexible chamber comprises a processing chamber (see page 6, lines 2-5). Regarding claim 5, the flexible chamber comprises a processing chamber (see page 6, lines 2-5). Regarding claim 6, the expandable wall comprises an accordion wall (see Fig. 9). Regarding claim 8, the expandable wall includes a plurality of pairs of partitions (see Fig. 9). Regarding claims 9 and 11, WO ‘451 discloses a processing apparatus comprising a flexible chamber (31,32,41,42,71,72,81 or 82; or a plurality thereof) comprising a first side (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side may be considered the left side of the hub) with an axial opening (such as 23 or 63) and a second side (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side may be considered the right side of the hub) with an axial opening (such as 23 or 63), wherein a first end of the expandable wall is attached to a circumference of the first side of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one

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pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3), wherein a first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber and wherein a second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber (see Fig. 3), wherein the chamber is sterilized (see page 1, lines 11-13; page 5, line 25) and adaptable to a continuous centrifuge (see page 2, lines 5-6). Regarding claim 12, the expandable wall is an accordion wall (see Fig. 9). Regarding claim 14, the expandable wall includes a plurality of pairs of partitions (see Fig. 9). Regarding claim 15, the flexible chamber comprises a processing chamber (see page 6, lines 2-5). Regarding claim 16, the flexible chamber comprises an expressor chamber (see page 6, lines 2-5). Regarding claim 17, there are plural flexible chambers (see page 6, lines 2-28). Regarding claim 18, the apparatus has a processing chamber and an expressor chamber (see page 6, lines 2-28). Regarding claim 19, WO '451 discloses a continuous flow centrifuge (see page 2, lines 5-6) comprising a plurality of flexible chambers (see page 6, lines 2-28), each flexible chamber (31,32,41,42,71,72,81 or 82; or a plurality thereof) comprising a first side (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side may be considered the left side of the hub) with an axial opening (such as 23 or 63) and a second side (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side may be considered the right side of the hub) with an axial opening (such as 23 or 63), wherein a first end of the expandable wall is attached to a circumference of the first side of the flexible chamber and a second

end of the expandable wall is attached to a circumference of the second side of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3), wherein a first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber and wherein a second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber (see Fig. 3), wherein at least one of the plurality of flexible chambers is sterilized (see page 1, lines 11-13; page 5, line 25). Regarding claim 20, WO '451 discloses a biological cell processing apparatus comprising a continuous flow centrifuge (see page 2, lines 5-6) and a sterilized (see page 1, lines 11-13; page 5, line 25) flexible chamber (31,32,41,42,71,72,81 or 82; or a plurality thereof) comprising a first side (for example, considering flexible chamber 32 as depicted in Fig. 3, the first side may be considered the left side of the hub) with an axial opening (such as 23 or 63) and a second side (for example, considering flexible chamber 32 as depicted in Fig. 3, the second side may be considered the right side of the hub) with an axial opening (such as 23 or 63), wherein a first end of the expandable wall is attached to a circumference of the first side of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber (see for example Fig. 3), wherein the expandable wall includes at least one pair of corresponding partitions (for example the left and right halves of the expandable wall of 32 as depicted in Fig. 3), wherein a first partition of the pair of partitions includes

a first circumferential end attached to the circumference of the first side of the flexible chamber and wherein a second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber (see Fig. 3).

7. Claims 1, 4-6, 8, 9, 11, 12 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Knoll et al. (US 5,242,398). Regarding claim 1, Knoll ('398) discloses a flexible chamber (sheath 24, or a portion thereof) comprising a first side (one end portion of sheath 24) with an axial opening and a second side (the other end portion of sheath 24) with an axial opening, wherein a first end of the expandable wall (a middle portion of a sheath 24; see col. 5, lines 59-67) is attached to a circumference of the first side of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber, wherein the expandable wall includes at least one pair of corresponding partitions (two adjacent pleats 28), wherein a first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber and wherein a second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber (see Fig. 1), wherein the flexible chamber is sterilized (see col. 1, lines 5-10; col. 3, line 55). While the reference does not involve a centrifuge, a centrifuge is not part of the claimed structure and "the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself" *In re Casey*, 152 USPQ 235 (CCPA 1967). Regarding claim 4, the flexible chamber comprises a processing chamber (see Fig. 1).



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Regarding claim 5, the flexible chamber comprises a processing chamber (see Fig. 1). Regarding claim 6, the expandable wall comprises an accordion wall (see col. 5, lines 59-67). Regarding claim 8, the expandable wall includes a plurality of pairs of partitions (see Fig. 1; col. 5, lines 59-67). Regarding claims 9 and 11, Knoll ('398) discloses processing apparatus comprising a flexible chamber (sheath 24, or a portion thereof) comprising a first side (one end portion of sheath 24) with an axial opening and a second side (the other end portion of sheath 24) with an axial opening, wherein a first end of the expandable wall (a middle portion of a sheath 24; see col. 5, lines 59-67) is attached to a circumference of the first side of the flexible chamber and a second end of the expandable wall is attached to a circumference of the second side of the flexible chamber, wherein the expandable wall includes at least one pair of corresponding partitions (two adjacent pleats 28), wherein a first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber and wherein a second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber (see Fig. 1), wherein the flexible chamber is sterilized (see col. 1, lines 5-10; col. 3, line 55). While the reference does not involve a centrifuge, a centrifuge is not part of the claimed structure and "the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself" *In re Casey*, 152 USPQ 235 (CCPA 1967). Regarding claim 12, the expandable wall is an accordion wall (see col. 5, lines 59-67). Regarding claim 14, the expandable wall includes a plurality of pairs of partitions (see Fig. 1; col. 5, lines 59-67). Regarding claim 15, the

flexible chamber comprises a processing chamber (see Fig. 1). Regarding claim 16, the flexible chamber comprises an expressor chamber (see Fig. 1). Regarding claim 17, there are plural flexible chambers (each being a section of sheath 24). Regarding claim 18, the apparatus has a processing chamber and an expressor chamber (each being a section of sheath 24).

### ***Response to Arguments***

8. Applicant argues that "Flexibility alone does not mean that the walls of the '451 reference are able to increase in extent or size as do~~g~~ the expandable walls of Applicant's claimed invention". However, WO '451 expressly states on page 2, line 11, that the chambers are "expandable". See also page 2, line 23 "expandable" and page 7, line 4, "inflation or expansion".

9. Applicant points out that the adjacent, circumferentially joined flexible sheets of WO '451 have nothing attached between. However, a pair of adjacent circumferentially attached flexible sheets are a pair of partitions which constitute an expandable wall and which are attached circumferentially to sides, as required by the claims.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 7:30-4:00 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
David L. Sorkin  
Primary Examiner  
Art Unit 1797

DLS